REMARKS

Claims 1-13 and 48-64 were examined. No claims are amended. Claims 1-13 and 48-64 remain in the application.

The Patent Office rejects claims 1-13 and 48-64 under 35 U.S.C. §103(a). Reconsideration of the pending claims is respectfully requested in view of the above amendments and the following remarks.

A. 35 U.S.C. §103(a): Rejection of Claims 1-9, 12-13 & 48-60

The Patent Office rejects claims 1-9, 12-13 and 48-60 under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 4,192,320 issued to Boddie (Boddie) in view of U.S. Patent No. 4,540,402 issued to Aigner (Aigner).

Boddie describes a technique for isolating a liver to allow chemotherapy treatment. Boddie does not say specifically how its system is installed in a body. However, there are clues that indicate installation is by way of an open chest cavity procedure. For example, Boddie describes securing catheters to vessels. Col. 2, lines 25-28 (first branch catheter 35); col. 2, lines 29-32 (second branch catheter 36). Boddie also describes ligatures used to hold catheters. Col. 3, lines 29-38. Boddie also preferably chooses a ligature to occlude blood flow into the liver from the hepatic artery. Col. 3, lines 40-42. No other blood flow occlusion is described.

Aigner describes a perfusion catheter of a splint catheter of a smaller catheter for isolating the liver without disrupting circulation through the vena cava and the vena portae permitting withdrawal blood from the liver. Similar to Boddie, Aigner does not specifically say how the catheter is installed in a body. However, there are clues that indicate installation is by way of open chest cavity. First, the splint catheter has a length of 250 mm (about 10 inches). Col. 2, line 12. Second, the entire length of the splint catheter fits in the vena cava. Col. 4, lines 42-43. Aigner teaches ligating the vessels from the outside. Col. 4, lines 43-45. Alternatively, a balloon may be used on the catheter mounted from the outside. (Col. 4, lines 49-52).

Independent claim 1 describes a system including a delivery conduit and a collection conduit. The delivery conduit has a length dimension suitable to be positioned from a first

externally accessible channel of a patient adjacent to or into at least one upstream channel of the biological mass by way of a percutaneous transluminal route. The collection conduit has a length dimension suitable to be positioned from a second externally accessible channel of a patient adjacent to or into at least one downstream channel of the biological mass by way of a percutaneous transluminal route.

Claim 1 provides specific structural limitations to the delivery conduit and the collection conduit. The length dimension is defined in terms of externally accessible channels of a patient. A second structural limitation of each of the delivery conduit and the collection conduit is that they have a dimension, e.g., diameter, that allows each conduit to be positioned by way of a percutaneous transluminal route.

Claim 1 is not obvious over the cited references because the references do not describe a delivery conduit and a collection conduit each having a length dimension as noted and a dimension suitable to be positioned by way of a percutaneous transluminal route. It may be that placing a catheter within a blood vessel during an open chest cavity procedure constitutes "percutaneous transluminal" at least where the blood vessel is opened and the catheter inserted. However, such a procedure does not account for the length dimension as positioned from an externally accessible channel of a patient to a desired position by way of a percutaneous transluminal route. Further, an opened chest cavity procedure to access a blood vessel does not make the blood vessel externally accessible.

Claim 1 is further not obvious over the cited references because there is no motivation to combine the teachings of Aigner with Boddie to obtain the system of claim 1. Boddie teaches introducing chemotherapy agents 20 through first branch catheter 35 inserted into and conformably engaged with the hepatic artery. Col. 2, lines 23-28. Upstream of the entry point of first branch catheter into the hepatic artery, the hepatic artery is occluded (to prevent blood flow into the liver). See Figure 3. The occlusion is preferably done by a ligature. Col. 3, lines 4-42. To substitute a balloon for the ligature preferred by Boddie, one presumably would have to branch first branch catheter 35 in a direction downstream (toward liver) and a position upstream. The upstream directed branch would contain the balloon catheter portion. Such a branched device is far beyond the teachings of Aigner or Boddie. It is also not clear if a ligature would not

still be necessary to stop blood flow while the branched device was placed. In such case, if a ligature is necessary, there is no reason for a balloon.

The other ligatures of Boddie appear to teach conformally engaging and releasably holding catheters to arteries or veins, not to block them. Accordingly, substituting a balloon for a ligature would not be suitable.

For the above stated reasons, claim 1 is not obvious over the cited references. Claims 2-9 and 12-13 depend from claim 1 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 1, claims 2-9 are not obvious over the cited references.

Independent claim 48 describes a system including a delivery conduit, a collection conduit, and a fluid to be administered to a biological mass through the delivery conduit and collected by the collection conduit. The delivery conduit has a length dimension suitable to be positioned by a percutaneous transluminal route from a first externally accessible channel of a patient. The collection conduit also has a dimension suitable to be positioned by percutaneous transluminal route from a second externally accessible channel of a patient.

Claim 48 is not obvious over the cited references, because the cited references do not describe a delivery conduit or a collection conduit having a length dimension suitable to be positioned by percutaneous transluminal route from an externally accessible channel of a patient. As noted above, with respect to claim 1, Boddie and Aigner both appear to describe open chest cavity procedures to access blood vessels of a patient, i.e., not by way of externally accessible channels. Further, since Boddie and Aigner proceed by an apparent open chest cavity procedure, there is no requirement that the catheters in those references have a dimension suitable to be positioned by percutaneous transluminal route from an externally accessible channel.

Claim 48 is further not obvious over the cited references because there is no motivation to combine the teachings of Aigner and Boddie to obtain the system of claim 48. As noted above with respect to claim 1, it does not appear practical or even feasible to achieve the occluding of the hepatic artery by adding a balloon to first branch catheter 35 of Boddie to replace the

preferred ligature. Further, none of the other ligatures described by Boddie are used as occlusive devices.

Claims 49-60 depend from claim 48 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 48, claims 49-60 are not obvious over the cited references.

Applicant respectfully requests the Patent Office withdraw the rejection to claims 1-9, 12-13 and 48-60 under 35 U.S.C. §103(a).

B. 35 U.S.C. §103(a): Rejection of Claims 10-11

The Patent Office rejects claims 10-11 under 35 U.S.C. §103(a) as obvious over Boddie in view of Aigner. Claims 10-11 depend from claim 1 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 1, claims 10-11 are not obvious. Further, both Boddie and Aigner deal with isolating the liver. Neither reference provides a teaching or motivation for isolating a portion of the human heart. Applicant respectfully requests that the Patent Office withdraw the rejection to claims 10-11 under 35 U.S.C. §103(a).

C. Claims 61-64

The Patent Office rejects claims 61-64 over Boddie in view of Aigner in further in view of U.S. Patent No. 5,452,733 of Sterman et al. (Sterman). Boddie and Aigner are cited for their teachings noted with respect to the other claims. Sterman is cited for teaching a method of accessing a heart with a catheter via a jugular vein (i.e., a percutaneous transluminal route). In other words, the Patent Office believes it would be obvious to modify the open chest cavity technique of Boddie and Aigner with a closed cavity (percutaneous transluminal) technique of Sterman.

Claims 61-62 depend from claim 1 and claims 63-64 depend from claim 48. For at least the reason stated with respect to claims 1 and 48, claims 61-64 are not obvious over the cited references. Further, there is absolutely no suggestion in Sterman that its closed chest cavity procedure for performing, for example, coronary bypass grafts, may be utilized in the liver treatment technique described in Boddie.

For the above stated reasons, Applicant respectfully requests that the Patent Office withdraw the rejection to claims 61-64 over the cited references.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

Respectfully submitted,

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William Thomas Babbitt, Reg. No. 39,591

12400 Wilshire Boulevard
Seventh Floor
Los Angeles, California 90025
(310) 207-3800

I hereby certify that this correspondence is being transmitted via facsimile to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Nedy Calderon 1/31/05
Nedy Calderon Date

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